

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARVIN A. EATON, Individually and on Behalf of All Others Similarly Situated,	:	
	:	Case No. 1:14-cv-06069-LGS
Plaintiff(s),	:	
	:	
v.	:	
	:	
EDAP TMS S.A., MARC	:	
OCZACHOWSKI, and ERIC SOYER,	:	
Defendants.	:	
	:	
RONNIE HADDAD, Individually and on Behalf of All Others Similarly Situated,	:	Case No. 1:14-cv-06188-LGS
	:	
Plaintiff(s),	:	
	:	
v.	:	
	:	
EDAP TMS S.A., MARC	:	
OCZACHOWSKI, and ERIC SOYER,	:	
Defendants.	:	

MEMORANDUM OF LAW IN SUPPORT OF THE MOTION BY
RYAN H. TENNEBAR FOR CONSOLIDATION, APPOINTMENT AS LEAD
PLAINTIFF, AND APPROVAL OF COUNSEL

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Ryan H. Tennebar (“Tennebar”) respectfully submits this Memorandum of Law in support of his motion, pursuant to Section 21D(a)(3) of the Securities Exchange Act of 1934 (the “Exchange Act”), as amended by the Private Securities Litigation Reform Act of 1995 (the “PSLRA”), 15 U.S.C. § 78u-4(a)(3), and Rule 42 of the Federal Rules of Civil Procedure, for the entry of an Order: (1) consolidating the above-captioned actions (the “Related Actions”); (2) appointing Tennebar as Lead Plaintiff on behalf of all persons who purchased or otherwise acquired the American Depositary Receipts (“ADRs”) of EDAP TMS S.A., (“EDAP” or the “Company”) on the NASDAQ Exchange from February 1, 2013 to July 30, 2014, inclusive (the “Class Period”); (3) approving Lead Plaintiff’s selection of Pomerantz LLP (“Pomerantz”) as Lead Counsel for the Class; and, (4) granting such other and further relief as the Court may deem just and proper.

I. PRELIMINARY STATEMENT

Pursuant to the PSLRA, the court appoints as lead plaintiff the movant who possesses the largest financial interest in the outcome of the action and who satisfies the requirements of Rule 23 of the Federal Rules of Civil Procedure. 15 U.S.C. § 78u-4(a)(3)(B)(iii)(I). Tennebar, with losses of approximately \$201,577 in connection with his purchases of EDAP securities during the Class Period, has the largest financial interest in the relief sought in this action. Tennebar further satisfies the requirements of Rule 23 of the Federal Rules of Civil Procedure as he is an adequate representative with claims typical of the other Class members. Accordingly, Tennebar respectfully submits that he should be appointed Lead Plaintiff.

II. STATEMENT OF FACTS

Defendant EDAP TMS S.A., through its subsidiaries, designs and manufactures medical equipment. The Company develops minimally invasive therapeutic ultrasound solutions for urology, tumor removal, localized prostate cancer, and related infectious diseases. EDAP

purports to serve patients and medical professionals worldwide. EDAP is incorporated and headquartered in France and its ADR's trade on the NASDAQ under the ticker symbol "EDAP."

One of the most important therapeutic solutions in the Company's pipeline is Ablatherm, a HIFU-based device for the treatment of organ-confined prostate cancer, referred to as T1-T2 stage. The Ablatherm system is intended to treat prostate cancer by ablating the entire prostate gland via high intensity focused ultrasound ("HIFU"), which generates heat of around 200 degrees Fahrenheit. There are no other HIFU devices on the market. Most men with the condition are treated with radical prostatectomy surgery, radiation or regular monitoring with delayed surgery if needed, according to the FDA.

Throughout the Class Period, Defendants made false and/or misleading statements, and failed to disclose material adverse facts about the Company's business, operations, prospects and performance. Specifically, during the Class Period, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company was overstating the efficacy and safety of its Ablatherm trials by using faulty statistical methods and presenting misleading data; (ii) the Company was understating the frequency of adverse events in its trials for Ablatherm including erectile dysfunction, urinary incontinence, and urethral and bowel injury; and (iii) as a result of the above, the Company's financial statements were materially false and misleading at all relevant times.

On July 28, 2014, a U.S. Food and Drug Administration ("FDA") staff report was released in anticipation of a July 30, 2014 meeting of the Gastroenterology and Urology Devices Panel Advisory Committee meeting (the "FDA Staff Report"). In the FDA Staff Report, the FDA questioned whether EDAP's methods for testing the device were adequate. Specifically, FDA staff questioned EDAP's safety and effectiveness data because the Company compared

patients in two different studies to gather evidence, rather than a head-to-head trial. EDAP relied on a registry of patients in Europe who have used Ablatherm, and compared their data to a subgroup of patients in a U.S. Department of Veterans Affairs trial who underwent surgery called radical prostatectomy. Patients who used Ablatherm had a 1.1 percent risk of their cancer spreading after eight years, compared to a 1.4 percent risk for men who underwent surgery.

According to an article published by Bloomberg News on July 28, 2014:

[The] FDA staff report raises concerns about “clinical meaningfulness” of EDAP’s data and safety of its Ablatherm Integrated Imaging device to treat low-risk, localized prostate cancer.

- ☐ FDA cites concerns about how efficacy data were interpreted in application, limitations in cross-study comparisons, safety profile and comparisons of the non-surgical device.
- ☐ FDA advisory panel will meet July 30 to review findings and make recommendations.

The FDA Staff Report also noted high rates of adverse events associated with Ablatherm, including erectile dysfunction and urinary incontinence, clinically significant rates of stricture, urethral injury and bowel injury, which the Company had not properly presented in a clinically meaningful way. Specifically, the FDA Staff Report notes:

FDA Comment: Several of the separately-reported adverse event categories are related, and may be more clinically meaningful for interpretation when combined, as follows: “voiding symptoms” (e.g., bladder/urinary urgency, urinary frequency, hesitancy, incomplete bladder emptying, irritative symptoms, nocturia, lower urinary tract symptoms, etc.), “urinary retention” (e.g., urinary restriction, retention, obstruction, etc.), “stricture” (e.g., urinary stricture, urethral stenosis, bladder neck contracture, etc.), “bowel dysfunction” (e.g., constipation, diarrhea, hemorrhoidal pain, nausea, vomiting, ischemic bowel, rectal bleeding, etc.), and “urethral injury” (e.g., urethral perforation, sloughing, submucosal hematoma, etc.).

Also, on July 28, 2014, as a result of the FDA Staff Report, EDAP was downgraded to “Market Perform” from “Outperform” at Northland Securities by equity analyst Suraj Kalia.

On the news, EDAP stock fell \$1.23 in unusually heavy volume, or over 25%, to close at \$3.65 on July 28, 2014.

On July 30, 2014, after the close of trading, the Company issued a press release and filed a Form 6-K with the SEC, providing an update on the FDA Advisory Committee Meeting on Ablatherm. In the press release, the Company stated, in part:

EDAP TMS SA (Nasdaq: EDAP), the global leader in therapeutic ultrasound, today announced that the U.S. Food and Drug Administration's (FDA) Gastroenterology and Urology Devices Panel (GUDP) voted 3 yes, 5 no with 1 abstention on the question of safety, 9 no on the question of efficacy, and 8 no with 1 abstention for the risk/benefit ratio for the use of its Ablatherm-HIFU device for the treatment of low-risk, localized prostate cancer.

Marc Oczachowski, EDAP's Chief Executive Officer, commented, "We are disappointed by the Committee's recommendation regarding Ablatherm-HIFU for the treatment of low-risk, localized prostate cancer and we appreciate the dialogue during today's meeting. We look forward to subsequent discussion with the FDA. We will continue to work diligently with the FDA as it carefully completes its final review for Ablatherm-HIFU's PMA."

On the news, EDAP stock fell \$1.50 on unusually heavy volume, or almost 44%, to close at \$1.92 on July 31, 2014.

III. ARGUMENT

A. THE RELATED ACTIONS SHOULD BE CONSOLIDATED

Consolidation of related cases is appropriate, where, as here, the actions involve common questions of law and fact, and therefore consolidation would avoid unnecessary cost, delay and overlap in adjudication:

Where actions involving a common question of law or fact are pending before the court, it may order a joint hearing or trial of any or all of the matters at issue in the actions; it may order all the actions consolidated; and it may make such order concerning proceedings therein as may tend to avoid unnecessary costs or delay.

Fed. R. Civ. P. 42(a). *See also* Manual for Complex Litigation (Third), § 20.123 (1995).

Moreover, the PSLRA also calls for consolidation where “more than one action on behalf of a class asserting substantially the same claim or claims arising under this chapter has been filed....” *Blackmoss Invs., Inc. v. ACA Capital Holdings, Inc.*, 252 F.R.D. 188 (S.D.N.Y. 2008). Here, the Related Actions allege claims against the same defendants, stemming from the same set of misconduct. Accordingly, consolidation of the Related Actions is appropriate. *Lintz v. Agria Corp.*, 2008 U.S. Dist. LEXIS 99846 (S.D.N.Y. Dec. 3, 2008) (consolidating actions that all alleged federal securities law violations arising out of defendants’ alleged issuance of false and misleading financial statements).

B. TENNEBAR SHOULD BE APPOINTED LEAD PLAINTIFF

Section 21D(a)(3)(B) of the PSLRA sets forth procedures for the selection of a lead plaintiff in class actions brought under the Exchange Act. The PSLRA directs courts to consider any motion to serve as lead plaintiff filed by class members in response to a published notice of class action by the later of (i) 90 days after the date of publication, or (ii) as soon as practicable after the Court decides any pending motion to consolidate. 15 U.S.C. § 78u-4(a)(3)(B)(i) &(ii).

Further, under 15 U.S.C. § 78u-4(a)(3)(B)(iii)(I), the Court is directed to consider all motions by plaintiffs or purported class members to appoint lead plaintiff filed in response to any such notice. Under this section, the Court “shall” appoint “the presumptively most adequate plaintiff” to serve as lead plaintiff and shall presume that plaintiff is the person or group of persons, that:

(aa) has either filed the complaint or made a motion in response to a notice . . .;

(bb) in the determination of the Court, has the largest financial interest in the relief sought by the class; and

(cc) otherwise satisfies the requirements of Rule 23 of the Federal Rules of Civil Procedure.

15 U.S.C. § 78u-4(a)(3)(B)(iii)(I).

As set forth below, Tennebar satisfies all three of these criteria and thus is entitled to the presumption that he is the most adequate plaintiff of the Class and, therefore, should be appointed Lead Plaintiff for the Class.

1. Tennebar is Willing to Serve as a Class Representative

On August 4, 2014, counsel in the first-filed action caused a notice (the “Notice”) to be published over *GLOBE NEWSWIRE* pursuant to Section 21D(a)(3)(A)(i) of the PSLRA, which announced that a securities class action had been filed against the defendants herein, and advised investors of EDAP securities that they had until October 3, 2014, to file a motion to be appointed as Lead Plaintiff. *See* Notice, Ex. A.

Tennebar has filed the instant motion pursuant to the Notice, and has attached the requisite certification attesting that he is willing to serve as class representative for the Class and provide testimony at deposition and trial, if necessary. *See* Certification, Ex. B. Accordingly, Tennebar satisfies the first requirement to serve as Lead Plaintiff for the Class.

2. Tennebar has the “Largest Financial Interest”

The PSLRA requires a court to adopt a rebuttable presumption that “the most adequate plaintiff . . . is the person or group of persons that . . . has the largest financial interest in the relief sought by the class.” 15 U.S.C. § 78u-4(a)(3)(B)(iii). *Varghese v. China Shenghuo Pharm. Holdings, Inc.*, 589 F. Supp. 2d 388, 394-395 (S.D.N.Y. 2008); *In re Donkenny, Inc. Sec. Litig.*, 171 F.R.D. 156, 157 (S.D.N.Y. 1997).

As of the time of the filing of this motion, Tennebar believes that he has the largest financial interest of any of the Lead Plaintiff movants based on the four factors articulated in the seminal case *Lax v. First Merchants Acceptance Corp.*, 1997 WL 461036, at *5 (N.D. Ill. 1997) (financial interest may be determined by (1) the number of shares purchased during the class

period; (2) the number of net shares purchased during the class period; (3) the total net funds expended during the class period; and (4) the approximate losses suffered).¹ Most courts agree that the approximate loss suffered is the most significant of the four elements. *See, e.g., Richman v. Goldman Sachs Group, Inc.*, No. 10 Civ. 03461(PAC), 2011 WL 2360291, at *6 (S.D.N.Y. March 25, 2011) (“Most courts agree that the largest loss is the critical ingredient in determining the largest financial interest”); *Foley v. Transocean Ltd.*, 272 F.R.D. 126, 128 (S.D.N.Y. 2011) (“[W]e, as have other courts, shall place the most emphasis on the last of the four factors, the approximate loss suffered by the movant”).

During the Class Period, (1) Tennebar purchased 75,020 ADRs of EDAP; (2) expended \$317,674 on his purchases; (3) retained all 75,020 ADRs of EDAP at the end of the Class Period; and, (4) as a result of the revelations of the fraud, Tennebar suffered a loss of \$201,577. *See* Loss Chart, Ex. C. Because Tennebar possesses the largest financial interest in the outcome of this litigation, he may be presumed to be the “most adequate” plaintiff. 15 U.S.C. § 78u-4(a)(3)(B)(iii)(I)(bb); *see also Chilton v. Chiumento Group*, 365 Fed. App’x 298, 299 (2d Cir. 2010) (discussing qualifications for Lead Plaintiff presumption); *In re Bank of Am. Corp. Sec., Deriv. and ERISA Litig.*, 258 F.R.D. 260, 268 (S.D.N.Y. 2009).

3. Tennebar Otherwise Satisfies the Requirements of Rule 23 of the Federal Rules of Civil Procedure

Section 21D(a)(3)(B)(iii)(I)(cc) of the PSLRA further provides that, in addition to possessing the largest financial interest in the outcome of the litigation, a Lead Plaintiff must “otherwise satisfy the requirements of Rule 23 of the Federal Rules of Civil Procedure.” 15 U.S.C. § 78u-4(a)(3)(B)(iii)(I)(cc); *see also In re Elan Corp. Sec. Litig.*, No. 02 Civ. 865 (WK)

¹ *See also In re Olsten Corp. Sec. Litig.*, 3 F. Supp.2d 286, 296 (E.D.N.Y. 1998). *Accord In re Comverse Tech., Inc., Sec. Litig.*, 2007 U.S. Dist. LEXIS 14878, at *22-*25 (E.D.N.Y. Mar. 2, 2007) (collectively, the “*Lax-Olsten*” factors.).

(FM), 2002 U.S. Dist. LEXIS 23162, at *7 (S.D.N.Y. Dec. 3, 2002); *Albert Fadem Trust v. Citigroup Inc.*, 239 F. Supp. 2d 344, 347 (S.D.N.Y. 2002). Rule 23(a) generally provides that a class action may proceed if the following four requirements are satisfied:

(1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

In making its determination that Lead Plaintiff satisfies the requirements of Rule 23, the Court need not raise its inquiry to the level required in ruling on a motion for class certification; instead a *prima facie* showing that the movant satisfies the requirements of Rule 23 is sufficient. *See Canson v. WebMD Health Corp.*, No. 11-cv-5382-JFK, 2011 WL 5331712, at *4 (S.D.N.Y. Nov. 7, 2011). Moreover, “typicality and adequacy of representation are the only provisions relevant to a determination of lead plaintiff under the PSLRA.” *In re Oxford Health Plans, Inc. Sec. Litig.*, 182 F.R.D. 42, 49 (S.D.N.Y. 1998) (citing *Gluck v. Cellstar Corp.*, 976 F. Supp. 542, 546 (N.D. Tex. 1997); *Olsten.*, 3 F. Supp. 2d at 296 (quoting *In re Drexel Burnham Lambert Group, Inc.*, 960 F.2d 285, 291 (2d Cir. 1992)).

The typicality requirement of Fed. R. Civ. P. 23(a)(3) is satisfied where the named representative’s claims are typical of the class’ claims. *In re EVCI Career Colleges Holding Corp. Sec. Litig.*, No. 05-cv-10240-CM, 2007 WL 2230177, at *13 (S.D.N.Y. July 27, 2007) (“[t]ypicality does not require that the factual background of each named plaintiffs claim be identical to that of all class members.”).

Tennebar’s claims are typical of those of the Class. Tennebar alleges, as do all class members, that defendants violated Federal Securities Laws by making what they knew or should have known were false or misleading statements of material facts concerning EDAP, or omitted

to state material facts necessary to make the statements they did make not misleading. Tennebar, as did all members of the Class, purchased EDAP securities during the Class Period at prices artificially inflated by defendants' misrepresentations or omissions and was damaged upon the disclosure of those misrepresentations and/or omissions. These shared claims, which are based on the same legal theory and arise from the same events and course of conduct as the Class claims, satisfy the typicality requirement of Rule 23(a)(3).

The adequacy of representation requirement of Rule 23(a)(4) is satisfied where it is established that a representative party "will fairly and adequately protect the interests of the class." The class representative must also have sufficient interest in the outcome of the case to ensure vigorous advocacy. *See Xianglin Shi v. Sina Corp.*, No. 05-cv-2154-NRB, 2005 WL 1561438, at *3 (S.D.N.Y. July 1, 2005); *Ghodooshim v. Qiao Xing Mobile Commc'n Co., Ltd.*, No. 12-cv-9264-JSR, 2013 WL 2314267 (S.D.N.Y. May 21, 2013); *Beck v. Maximus*, 457 F.3d at 296 (emphasizing that the adequacy inquiry "serves to uncover conflicts of interest between named parties and the class they seek to represent," (quoting *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625 (1997))).

Tennebar adequately represents the Class. There is no antagonism between Tennebar's interests and those of the Class, and his losses demonstrate that he has a sufficient interest in the outcome of this litigation. Moreover, Tennebar has retained counsel highly experienced in vigorously and efficiently prosecuting securities class actions such as this action, and submits his choice to the Court for approval pursuant to 15 U.S.C. § 78u-4(a)(3)(B)(v).

4. Tennebar Will Fairly and Adequately Represent the Interests of the Class and is not Subject to any Unique Defenses

The presumption in favor of appointing Tennebar as Lead Plaintiff may be rebutted only upon proof “by a purported member of the plaintiffs’ class” that the presumptively most adequate plaintiff:

- (aa) will not fairly and adequately protect the interest of the class; or
- (bb) is subject to unique defenses that render such plaintiff incapable of adequately representing the class.

15 U.S.C. § 78u-4(a)(3)(b)(iii)(I).

Tennebar’s ability and desire to fairly and adequately represent the Class has been discussed above. Tennebar is not aware of any unique defenses defendants could raise that would render him inadequate to represent the Class. Accordingly, Tennebar should be appointed Lead Plaintiff for the Class.

C. LEAD PLAINTIFF’S SELECTION OF COUNSEL SHOULD BE APPROVED

The PSLRA vests authority in the Lead Plaintiff to select and retain lead counsel, subject to the approval of the Court. 15 U.S.C. § 78u-4(a)(3)(B)(v). The Court should interfere with Lead Plaintiff’s selection only when necessary “to protect the interests of the class.” 15 U.S.C. § 78u-4(a)(3)(B)(iii)(II)(aa). *See Varghese v. China Shenghuo Pharm. Holdings, Inc.*, 589 F. Supp. 2d 388, 398 (S.D.N.Y. 2008) (emphasizing that the PSLRA “evidences a strong presumption in favor of approving a properly-selected lead plaintiff’s decisions as to counsel selection and counsel retention.”).

Here, Tennebar has selected Pomerantz as Lead Counsel. Pomerantz is highly experienced in the area of securities litigation and class actions, and has successfully prosecuted numerous securities litigations and securities fraud class actions on behalf of investors as

detailed in the firm's resume. *See* Firm Resume, Ex. D. As a result of the firm's extensive experience in litigation involving issues similar to those raised in this action, Tennebar's counsel have the skill and knowledge which will enable them to prosecute this action effectively and expeditiously. Thus, the Court may be assured that by approving Tennebar's selection of Counsel, the members of the Class will receive the best legal representation available.

IV. CONCLUSION

For the foregoing reasons, Tennebar respectfully requests the Court to issue an Order: (1) consolidating the Related Actions; (2) appointing Tennebar as Lead Plaintiff; (3) approving Pomerantz as Lead Counsel; and, (4) granting such other relief as the Court may deem to be just and proper.

Dated: October 3, 2014
New York, New York

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